UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	**MDL No. 1456**
	)	**Master File No. 01-12257-PBS**
	)	**Subcategory Case No. 06-11337**
	)	
	)	**Judge Patti B. Saris**
THIS DOCUMENT RELATES TO: *State of California, ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.* Case No: 1:03-cv-11226-PBS	)	**Magistrate Judge Marianne B. Bowler**

PLAINTIFFS' SUR-REPLY IN OPPOSITION TO DEFENDANT MYLAN'S MOTION FOR PARTIAL SUMMARY JUDGMENT

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INTRODUCTION

None of Defendant Mylan's arguments establish a basis on which this Court may grant partial summary judgment. As to each of its five separate grounds, Mylan has failed to carry its burden of showing that there are no genuine issues of material fact for trial and that it is entitled to summary judgment as to any of Plaintiffs' claims.

I. CALIFORNIA'S CLAIMS ARE NOT BARRED BY THE STATUTE OF LIMITATIONS.

Mylan argues that California's claims are barred to the extent they accrued prior to July 1999—more than three years prior to Ven-A-Care's filing of its July 2002 Amended Complaint asserting claims against the Mylan Defendants. But Mylan has not borne its burden of showing that the California Attorney General's office had discovered or was on notice of the State's claims against Mylan by July 1999; hence, it is not entitled to summary judgment on this "factually intensive" inquiry. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 78 (D. Mass. 2007), *aff'd*, 582 F.3d 156 (1st Cir. 2009) (the "Bench Trial Ruling"). Further, even assuming, arguendo, that the State has the burden on this issue, there are factual questions as to when the limitations period began to run.

A. Mylan Improperly Ignores Recent Appellate Authority on the Limitations Period Applicable to CA FCA Claims.

The parties agree that the applicable statute of limitations bars any claim "filed more than three years after the date of discovery by the official of the state or political subdivision charged with responsibility to act in the circumstances or, in any event, no more than 10 years after the date on which the violation of Section 12651 is committed." CAL. GOV'T CODE § 12654(a). Given the limited number of cases addressing this statute, it is noteworthy that Mylan has totally ignored the most recent appellate case construing it. In *State ex rel. Hindin v. Hewlett-Packard Co.*, 153 Cal. App. 4th 307 (2007), the Court of Appeal held that the three year limitation period

of Section 12654(a) "commences in accord with the statutory language: [i.e.,] when the claim is discovered by 'the official of the state or political subdivision charged with responsibility to act in the circumstances,"—"the Attorney General, who has responsibility to act to protect the public fisc from false claims.'" *Id.* at 315; *see also* 314, 319.

Hindin is relevant here in two respects. First, the opinion holds that the Attorney General's office is the relevant entity whose knowledge triggers the running of the statute; the Court states that the phrase "'the official of the state or political subdivision charged with responsibility to act in the circumstances,' was intended to apply to a public official such as the Attorney General, who has responsibility to act to protect the public fisc from false claims." *Id.* at 315. *See also* similar language at 314, 319. Hence, Mylan's argument that Medi-Cal officials were on inquiry notice of potential claims against it is irrelevant.[1]

Second, the *Hindin* Court emphasized the plain meaning of the statutory language, which triggers the running of the limitations period on the "date of discovery," not when the responsible official was on inquiry notice of the violation. *Hindin* did not expressly overrule the notice standard articulated in *Debro v. The Los Angeles Raiders*, 92 Cal. App. 4th 940 (2001), but, at a minimum, it imposed a narrow reading on that standard. In that regard, the *Hindin* court expressly distinguished California law from the comparable provisions of the federal statute, stating: "the language of the federal statute of limitations differs significantly from the language of section 12654, subdivision (a). The federal statute dictates that the limitations period begins when material facts were 'known or reasonably should have been known. (31 U.S.C. §

[1] The statute was amended last year to codify this decision and now expressly states as follows: "A civil action under Section 12652 may not be filed more than three years after the date of discovery by the Attorney General . . . or, in any event, not more than 10 years after the date on which the violation of Section 12651was committed." CAL. GOV'T CODE. § 12654(a) (2009). But even if the prior version of the statute governs here, the *Hindin* court's construction leads to the same result.

3731(b)(2).) Section 12654, subdivision (a) states that the limitations period under the California Act begins upon 'discovery.'" *Id.* at 318. The Court went on to state that "there is no showing that the Attorney General was aware of the claim until it received Hindin's complaint, or that it learned of the underlying facts from other sources. Its 'discovery' of the claim thus occurred when the [qui tam] complaint was received . . ." *Id*. at 319.

In short, *Hindin* makes clear (1) that the limitations period does not begin to run until the Attorney General's office discovers the wrongdoing, since it is the agency with responsibility to act in the circumstances and (2) that, to the extent *Debro* retains viability outside of its particular context (involving claims arising from a major government contract, *the terms of which were negotiated by and known to the relevant government officials*), the CA FCA statute of limitations does not include the "reasonably should have known" standard of the Federal Act, but rather requires, at a minimum, the Attorney General's "knowledge of facts which could give rise to a false claim," *Debro*, 92 Cal. App. 4th at 952-53, to trigger the running of the limitations period.

B. Mylan Has the Burden of Showing that California's Claims Are Barred By the Statute of Limitations.

The general rule is that defendants bear the burden of pleading and proving affirmative defenses, such as the statute of limitations. "[B]ecause the statute of limitations is an affirmative defense, the defendant bears the burden of proving that the plaintiff filed beyond the limitations period." *Payan v. Aramark Mgmt. Servs. L.P.*, 495 F.3d 1119, 1122 (9th Cir. 2007); *see* FED. R. CIV. P. 8(C). In that regard, section 500 of the California Evidence Code provides that, "[e]xcept as otherwise provided by law, a party has the burden of proof as to each fact the existence or nonexistence of which is essential to the claim for relief or defense that he is asserting." Mylan asserted the affirmative defense of the statute of limitations and therefore has the burden of proving the underlying facts.

Relying on *Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal. 4th 797 (2005), Mylan argues that California bears the burden of showing that "it could not have discovered any claims that it may have had against Mylan before July 1999." That argument misstates California law. In *Fox*, the Plaintiff relied on the discovery rule to circumvent a statute of limitations that on its face barred her claims. The California Supreme Court held that where "*a complaint shows on its face that [plaintiff's] claim would be barred without the benefit of the discovery rule*," the plaintiff bears the burden of pleading and proving that she acted with reasonable diligence in investigating and pursuing her potential claims. *Id.* at 808 (emphasis added).

The instant complaint, however, does not "show on its face" that Plaintiffs' claims are time barred. Nothing in California's First Amended Complaint (or other pleadings) shows that the Attorney General had notice of the State's claims against Mylan prior to 2002, much less prior to July 1999.[2] Because the present complaint does *not* show on its face that California's claims are time barred, the normal rule applies, and Mylan bears the burden of alleging and proving its affirmative defense that the statute of limitations bars Plaintiffs' claims.

The governing case here is not *Fox*, but *Samuels v. Mix*, 22 Cal. 4th 1, 8 (1999). In *Samuels*, the California Supreme Court held that the defendant bore the burden of proving when the plaintiff discovered the facts making out her legal malpractice claim so as to trigger the running of the statute. The statutory language at issue in *Samuels* was, in all material respects, identical to the language at issue here, stating that, "'[a]n action against an attorney for a wrongful act or omission . . . shall be commenced within one year after the plaintiff discovers, or through the use of reasonable diligence should have discovered, the facts constituting the

2 As discussed below, neither the statute nor the case law support the notion that the Attorney General's awareness that certain pharmaceutical companies had engaged in AWP fraud was sufficient to put the State on notice that Mylan (or the hundreds of other companies whose products were reimbursed by Medi-Cal) had engaged in such fraud.

wrongful act or omission, or four years from the date of the wrongful act or omission, whichever occurs first.'" *Id.* at 5 (*quoting* CAL. CIV. PROC. CODE § 340.6.). The *Samuels* court held that the plain language of Section 340.6 brought the case within the general rule established by section 500 of the Evidence Code that Defendants bear the burden of making out an affirmative defense, including that of the statute of limitations. *Id*. at 7-8.[3]

The same principles apply here. The date the State discovered its claim against Mylan is not an element of Plaintiffs' prima facie claim under the CA FCA, but rather is an element of Mylan's affirmative defense. Mylan bears the burden of pleading (as it did) and proving (as it has not done, and cannot do) that defense.

C. The Evidence Does Not Show That the California Department of Justice Was on Notice of Claims Against Mylan Prior to July 1999.

Mylan relies on two pieces of evidence in support of its limitations argument: (1) the fact that the HHS OIG published a report in 1996 which, based on a limited survey, found that California pharmacists could purchase generic drugs, on average, for approximately 41.4% below their published AWPs, and (2) the fact that Ven-A-Care filed its original qui tam complaint in July 1998 against other defendants (not including Mylan). These facts do not bear the weight that Mylan places on them.

First, there is no evidence in the extensive record that officials from the California Attorney General's office were on notice of the 1996 OIG report. As discussed above, *Hindin* makes clear that the statute was tolled until such officials were on notice of a potential claim. Even if, arguendo, the OIG report were adequate to trigger the statutory period as to "all generic

3 The *Samuels* court expressly rejected the applicability of cases such as *Jolly v. Eli Lilly & Co.*, 44 Cal. 3d 1103 (1988), allocating burdens under the "discovery rule." The court explained that the discovery rule is an "exception" to the statute of limitations, whereas the alternate periods set forth within statutes like section 340.6 of the California Code of Civil Procedure and the CA FCA, CAL. GOV'T CODE § 12654, are actual statutes of limitation, as to which defendants bear the burden of proof. *Id*. at 10.

manufacturers" (which we dispute), the possibility that Medi-Cal personnel may have been aware of the OIG report was not enough to trigger the statutory period.

Second, Ven-A-Care's ("VAC") 1998 original Complaint against other pharmaceutical companies did not put the Attorney General's office on notice of potential claims against Mylan. The only logical inference that the office could draw from its review of VAC's original complaint and supporting data was that the companies specifically named therein might have been guilty of causing the submission of false claims by inflating AWPs, and that the hundreds of other pharmaceutical companies whose products Medi-Cal covered were apparently not engaged in such fraud.[4]

It is noteworthy in that regard that the original VAC Complaint particularly focused on infusion drugs and inhalant respiratory drugs, such as albuterol, not on the type of generic pills that Mylan manufactures. As paragraph 2 of the VAC Complaint states: "The specified pharmaceuticals are ordinarily sold by the DEFENDANT PHARMACEUTICAL MANUFACTURERS directly or through wholesalers *to physicians or outpatient clinics, such as oncology group physician practices, and to specialty infusion pharmacies, such as the Qui Tam Plaintiff, which then provide the drugs and biological and related supplies directly to the patient intravenously, by injection or inhalation.*" (Emphasis added.) The original Complaint did not put the Attorney General's office on notice that generic manufacturers of ordinary pills, like Mylan, were engaged in such fraud. In short, the inhalant-focused Complaint provided by VAC gave no hint that the State had potential claims against Mylan and could not trigger the running of the statute as to that company.

[4] This case cannot be analogized to cases where a Plaintiff has suffered a single injury and is held on notice to investigate claims against all actors. Here, California suffered multiple distinct and independent injuries from each Defendant's misconduct.

Finally, Mylan's reliance on this Court's findings in the Bench Trial Ruling that third party payors, such as Blue Cross, were on inquiry notice of AWP fraud by 1997, is misplaced. First, such a "factually intensive" matter should not be decided on summary judgment. Second, that ruling dealt with pricing of Medicare Part B drugs—a fundamentally different group of products than those are at issue here, as to which there were investigations and changes in reimbursement standards at the Federal level that are inapplicable to Mylan's products. Third, the level of knowledge that sophisticated third party payors, such as Blue Cross Blue Shield of Massachusetts [BCBSMA], had regarding pharmaceutical pricing is entirely irrelevant with respect to the controlling issue here—whether the California Attorney General's office was on notice of Mylan's reporting of fraudulent AWPs prior to July 1999.

As this Court found in its Bench Trial Ruling: "A reasonable plaintiff in BCBSMA's situation would be closely following any information that reported on drug reimbursement under Medicare. . . . BCBSMA, as a major insurer, would have monitored major Congressional actions regarding Medicare reimbursement policies." 491 F. Supp. 2d at 78-79. It seems obvious that one cannot assume that the California Attorney General's office monitored changes in Medicare reimbursement rates, much less with the level of attention that one could reasonably expect from major third party payors like BCBSMA. Mylan has failed to meet its burden of producing evidence that would even suggest, much less prove, that the Attorney General was on notice that Mylan was engaging in AWP fraud, so as to trigger the running of the statute. Accordingly, Mylan's motion should be denied.

II. MYLAN'S EVIDENCE DOES NOT SUPPORT ITS CLAIM THAT CALIFORNIA ONLY PAID MODEST DOLLAR PAYMENTS ABOVE PROVIDERS' COSTS

Mylan's claim that California only paid modest dollar payments above provider's costs is unfounded. The seven NDCs that Mylan selected for its motion for partial summary judgment

do not represent a sample that is indicative of reimbursement payments and dollar margins for drugs between 1994 through 2004. Unable to establish this fact, Mylan now argues that California paid "small margins" on the subject drugs by referring to certain calculations of its' expert David Bradford. According to Professor Bradford's calculations, the "average margin" California paid for all of the Mylan subject drugs was $3.54. (Mylan's Reply Br. at 8.)

However, as set forth in Plaintiffs' Opposition, the "average margin" was actually three times of what Mylan claims. The average amount of overpayment per claim was $9.00. Plaintiffs' expert Dr. Jeffrey Leitzinger concluded in his report that the total overpayment for Medi-Cal reimbursement of Mylan's identified pharmaceutical products for the period from January 1, 1994 through December 31, 2004 is $104.4 million. (Paul Mylan Decl. Ex. 14 (11/19/09 Leitzinger Decl. at Ex. A).[5]) Further, Exhibit 7 from Dr. Leitzinger's report represents the total number of Medi-Cal claims that make up the $104.4 million overpayment. There are a total of 11,661,056 claims. Thus, the average amount of overpayment per claim is $9. (Paul Opp. Decl. Ex. 25.[6])

None of Mylan's evidence can establish, as a matter of law, that California made only modest dollar payments above providers' costs. Accordingly, Mylan's motion for partial summary judgment on these grounds must also be denied.

[5] Declaration of Nicholas N. Paul in Support of Plaintiffs' Motion for Partial Summary Judgment as to Defendants Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. (docket no. 6690).

[6] Declaration of Nicholas N. Paul in Support of Plaintiffs' Opposition to Defendants' Joint Motion for Partial Summary Judgment (docket no. 6791).

III. OTHER GROUNDS

A. None of Plaintiffs' Claims in the Present Action Are Barred by the Res Judicata Effect of the Prior Antitrust Action.

The doctrine of res judicata does not bar this action. Notwithstanding this Court's ruling in *Massachusetts v. Mylan Labs*., No 03-11865-PBS, 2009 US Dist. LEXIS 20332 (D. Mass. March 11, 2009), Mylan has brought this summary judgment motion on the same facts and theory. Just as this Court denied its motion in the Massachusetts action, it should deny its motion here.

In its Reply, Mylan relies on *Tahoe Sierra Preservation Council, Inc. v. Tahoe Regional Planning Agency*, 322 F.3d 1064, 1077 (9th Cir. 2003) in contending that Plaintiffs are precluded by res judicata from asserting their claims in this action. The *Tahoe Sierra* case is easily distinguished. It involved two parties that had been litigating several lawsuits concerning the requirements of the 1987 plan adopted by the Tahoe Regional Planning Commission that was designed to preserve the beauty of Lake Tahoe by limiting development in designated areas. The Tahoe-Sierra Preservation Council, a property owners' association, filed a new action alleging wrongs it had unsuccessfully litigated before. *Id*. at 1076. In that case, the Court held that the association had a full opportunity to contest the provision of the 1987 plan in the prior litigation, and that those claims were, therefore, foreclosed by res judicata. *Id*. at 1086. The two actions at issue in *Tahoe Sierra* are fundamentally distinguishable from the Mylan antitrust actions to which Mylan points.

In the Mylan Antitrust Case, the Federal Trade Commission and several states sued Mylan Laboratories, Inc. and four other defendants under a conspiracy theory, alleging that Mylan conspired to obtain exclusive licenses with lorazepam and clorazepate API suppliers that barred other drug manufacturers' access to the lorazepam and clorazepate API, the most

significant ingredient in manufacturing tablets of the two drugs. By essentially controlling the only means to produce lorazepam and clorazepate in the United States, Mylan created a monopoly in the industry and manipulated the market by blocking any potential competition which resulted in an unreasonable restraint of trade. (CA Resp. Mylan SOF ¶¶ 1-3.[7]) The transactions in the Antitrust Case involved Mylan's attempts to control the supply of the API for lorazepam and clorazepate and Mylan's actions and agreements with its co-defendants (and API suppliers and brokers) Cambrex Corporation, Profarmaco S.r.1, Gyma Laboratories of America, Inc. and SST Corporation. (CA Resp. Mylan SOF ¶¶ 4-15.)

The present case has nothing to do with manipulation of the market for the ingredients of lorazepam and clorazepate or with Mylan's actions with Cambrex, Profarmaco, Gyma or SST. Rather, the gist of Plaintiffs' claims in this action is that Mylan reported false and inflated AWP prices to First DataBank, which were used by Medi-Cal to reimburse pharmacies for the subject drugs. (CA Resp. Mylan SOF ¶ 34.)

Unlike *Tahoe Sierra*, the claims in this action did not arise from the same transactional nucleus of facts of the Antitrust Case. Accordingly, Mylan's motion for partial summary judgment on these grounds must also be denied.

B. None of Plaintiffs' Claims in the Present Action are Barred by the Limited Release in the 2001 Settlement of the Antitrust Case.

Similarly, Mylan's argument that the Release in the Antitrust Case releases it from liability in the present case is also without merit. By the express terms of the Settlement Agreement, the only state statutory claims released were those "arising from the facts… set forth or alleged in the [Joint Third Amended Complaint.]" (CA Resp. Mylan SOF ¶¶ 21, 29-31.)

[7] Plaintiffs' Response to Defendants Mylan Inc. and Mylan Pharmaceutical Inc.'s Local Rule 56.1 Statement of Undisputed Facts in Support of Their Motion for Partial Summary Judgment and Plaintiffs' Statement of Additional Undisputed Facts In Opposition To Defendants' Motion For Partial Summary Judgment (docket no. 6783) (hereinafter "CA Resp. Mylan SOF").

California could not have alleged a violation of the CA FCA based on the "facts set forth or alleged in the [Joint Third Amended Complaint]." Accordingly, Mylan's motion for partial summary judgment on these grounds must also be denied.

C. Mylan Laboratories Inc. is a Proper Party in This Lawsuit.

Finally, Mylan argues that Mylan, Inc., formerly known as Mylan Laboratories, Inc., is not a proper party in this lawsuit because it is a holding company and did not manufacture, market, or sell any of the Mylan drugs at issue in this case. It argues that its wholly owned subsidiary, Mylan Pharmaceuticals, Inc., manufactured, marketed and sold the drugs at issue, and should be the only named Mylan entity defendant. However, there is a genuine issue of material fact as to whether Mylan Laboratories, Inc. (Mylan Inc.) manufactured, marketed and sold the drugs at issues in this case during the relevant time period. (CA Resp. Mylan SOF ¶¶ 35-38.)

Mylan cites *Freudensprung v. Offshore Tech. Servs., Inc.* 379 F.3d 327, 346-47 (5th Cir. 2004) in support of its argument that "[s]tatements about corporate subsidiaries in SEC filings are not sufficient to overcome the presumption of corporate separateness." (Mylan Reply Br. at 10.) California does not solely rely on the statements in Mylan's SEC filings, and *Freudensprung* does not stand for the proposition that such filings are irrelevant to issues of corporate identity.

Moreover, the case does not support the conclusion that Mylan draws from it. In *Freudensprung*, the Fifth Circuit held simply that the use of the general phrase "The Company" to refer to "Willbros Group Inc., and all of its majority owned subsidiaries" simply showed that there was some "corporate relationship between WWAI and the other Willbros entities," not that they were de facto one entity.

Here, by contrast, Mylan Laboratories, Inc. (Mylan Inc.) did not use a generic term like "The Company" to refer to Mylan Inc. and its subsidiaries, but rather expressly represented that

it is "engaged in developing, licensing, manufacturing, marketing and distributing generic and branded pharmaceutical products." (CA Resp. Mylan SOF ¶ 37.) The entire thrust of Mylan's 2003 SEC Form 10-K is that Mylan is a single business entity which is operated and controlled by Mylan Laboratories, Inc. (CA Resp. Mylan SOF ¶ 37.) Indeed, Mylan Inc. makes the statements that "[w]e conduct business through our generic . . . pharmaceutical operating segment[]" and "[w]e are recognized as a leader in the generic pharmaceutical industry." (*Id*.) The 10-K refers to Mylan Pharmaceuticals, Inc., its wholly owned subsidiary, as its "primary generic pharmaceutical...*division*." (*Id*.) (emphasis added). It also states that "[i]n fiscal 2003, Mylan [defined as Mylan Laboratories, Inc.] held the first or second market position in new and refilled prescriptions dispensed among all pharmaceutical companies in the U.S. with respect to 96 of the 133 generic pharmaceutical products we marketed, excluding unit dose products." (*Id.*)

All of these statements support the assertion that Mylan Laboratories, Inc. manufactured, marketed and sold pharmaceuticals during the relevant time period and is a proper defendant in this case. *Freudensprung* is not relevant given the very different description of the corporate relationships in the companies' respective SEC filings.

In addition to Mylan's SEC filings, Plaintiffs have presented organizational charts and testimony from Mylan representatives which also raise triable issues of fact that Mylan Laboratories, Inc. (Mylan, Inc.) controlled the marketing and sales of the Mylan drugs at issue in this case and, therefore, is a proper defendant. (CA Resp. Mylan SOF ¶ 38.) Accordingly, Mylan's motion for partial summary judgment on these grounds must also be denied.

CONCLUSION

For the foregoing reasons, Mylan has failed to carry its burden of showing that there are no genuine issues of material fact for trial and that it is entitled to summary judgment as to any

of Plaintiffs' claims. As a result, Mylan's Motion for Partial Summary Judgment should be denied in its entirety.

Dated: January 29, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on January 29, 2010, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ *Matthew C. Kilman*
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